Claims

1. Use of an immunogenic agent derived from *Helicobacter*, in the manufacture of a pharmaceutical composition intended for the induction of a T helper 1 (Th1) type immune response against *Helicobacter*, to prevent or treat a *Helicobacter* infection in a mammal.

2. Use according to Claim 1, in which the Th1-type immune response is characterized either (i) by a ratio of the ELISA IgG2a:IgG1 titers in mice greater than or equal to 1:100, or (ii) by a ratio of the ELISA IgG2a:IgA titers in mice greater than or equal to 1:100.

3. Use according to Claim 2, in which the Th1-type immune response is characterized either (i) by a ratio of the ELISA IgG2a:IgG1 titers in mice greater than or equal to 1:10, or (ii) by a ratio of the ELISA IgG2a:IgA titers in mice greater than or equal to 1:10.

4. Use according to Claim 3, in which the Th1-type immune response is characterized either (i) by a ratio of the ELISA IgG2a:IgG1 titers in mice greater than or equal to 1:2, or (ii) by a ratio of the ELISA IgG2a:IgA titers in mice greater than or equal to 1:2.

5. Use of an immunogenic agent derived from *Helicobacter*, in the manufacture of a pharmaceutical composition intended to be administered by the systemic route, in the part of a mammal, especially the primate, situated under its diaphragm, to treat or prevent a *Helicobacter* infection.

6. Use according to Claim 5, in which the composition is capable of inducing a Th1-type immune response when it is administered by the subdiaphragmatic systemic

route.

7. Use according to Claim 5 or 6, in which the Th1-type immune response is characterized either (i) by a ratio of the ELISA IgG2a: IgG1 titers greater than or equal to 1:100, or (ii) by a ratio of the ELISA IgG2a:IgA titers greater than or equal to 1 : 100.

8. Use according to Claim 7, in which the Th1-type immune response is characterized either (i) by a ratio of the ELISA IgG2a:IgG1 titers in mice greater than or equal to 1:10, or (ii) by a ratio of the ELISA IgG2a:IgA titers in mice greater than or equal to 1:10.

9. Use according to Claim 8, in which the Th1-type immune response is characterized either (i) by a ratio of the ELISA IgG2a:IgG1 titers in mice greater than or equal to 1:2, or (ii) by a ratio of the ELISA IgG2a:IgA titers in mice greater than or equal to 1:2.

10. Use according to one of Claims 1 to 9, in which the immunogenic agent derived from *Helicobacter* is selected from a preparation of inactivated *Helicobacter* bacteria, a *Helicobacter* cell lysate, a peptide, a polypeptide from *Helicobacter* in purified form, a DNA molecule comprising a sequence encoding a peptide or a polypeptide from *Helicobacter* placed under the control of the elements necessary for its expression and a vaccinal vector comprising a sequence encoding a peptide or a polypeptide from *Helicobacter* placed under the control of the elements necessary for its expression.

11. Use according to Claim 10, in which the immunogenic agent derived from *Helicobacter* is the UreB or UreA subunit of the *Helicobacter* urease.

12. Use according to Claim 10, in which the immunogenic agent derived from *Helicobacter* is a DNA molecule or a vaccinal vector comprising a sequence encoding the UreB or UreA subunit of the *Helicobacter* urease.

13. Use according to Claim 10, 11, or 12, in which the immunogenic agent is derived from *Helicobacter pylori*.

14. Use according to one of Claims 5 to 13, in which the pharmaceutical composition is intended to be administered by the strict systemic route.

15. Use according to one of Claims 5 to 14, in which the pharmaceutical composition is intended to be administered by a systemic route selected from the subcutaneous route, the intramuscular route, and the intradermal route.

16. Use according to one of Claims 5 to 14, in which the pharmaceutical composition is intended to be administered by a mucosal route followed by a parenteral route.

17. Use according to Claim 16, in which the pharmaceutical composition is intended to be administered by a parenteral route, followed by a mucosal route, followed by a parenteral route, followed by a mucosal route.

18. Use according to one of Claims 5 to 17, in which the pharmaceutical composition is intended to be administered in the dorsolumbar region of the said mammal.

19. Use according to one of Claims 5 to 18, in which the pharmaceutical composition is intended to be administered twice or three times by the systemic route

during the same treatment, in order to prevent or treat a *Helicobacter* infection.

20. Use according to one of Claims 5 to 18, in which the immunogenic agent is selected from a preparation of inactivated *Helicobacter* bacteria, a *Helicobacter* cell lysate, a peptide, a polypeptide from *Helicobacter* in purified form and is, in addition, combined with at least one compound capable of promoting the induction of a Th1-type immune response.

21. Use according to Claim 20, in which the compound capable of promoting the induction of a Th1-type immune response is selected from liposomes, microspheres, QS-21, DC-chol, and Bay R1005.

22. Use according to Claim 20, in which the compound capable of promoting the induction of a Th1-type immune response is selected from QS-21, DC-chol, and Bay R1005.

23. Use according to Claim 22, in which the immunogenic agent is combined with at least two compounds capable of promoting the induction of a Th1-type immune response; the first compound being selected from liposomes, microspheres and the second compound being selected from QS-21, DC-chol, and their equivalents.

24. Use according to Claim 20, in which the immunogenic agent is a peptide or a polypeptide which is combined, by covalent bonding, with at least one lipid capable of promoting the induction of a Th1-type immune response, so as to form a lipopeptide or lipid-containing polypeptide conjugate.

25. A method of preventing or treating *Helicobacter* infection in a mammal, said method comprising in order the steps of:

Sub B11

mucosally administering an immunogenic agent derived from *Helicobacter* to said mammal; and then

parenterally administering said immunogenic agent derived from *Helicobacter* to said mammal.

26. The method of claim 25, in which more than one mucosal administration is carried out.

27. The method of claim 25, in which more than one parenteral administration is carried out.

28. The method of Claim 25, in which the mucosal administration is carried out to prime an immune response to said immunogenic agent derived from *Helicobacter*, and the parenteral administration is carried out to boost an immune response to said immunogenic agent derived from *Helicobacter*.

29. The method of Claim 25 or 28, in which the mucosal administration is oral administration.

30. The method of Claim 25 or 28, in which the parenteral administration is intramuscular administration or subcutaneous administration.

31. The method of Claim 25, in which the immunogenic agent derived from *Helicobacter* is selected from a preparation of inactivated *Helicobacter* bacteria, a *Helicobacter* cell lysate, a peptide, a polypeptide from *Helicobacter* in purified form, a DNA molecule comprising a sequence encoding a peptide or a polypeptide from *Helicobacter* placed under the control of the elements necessary for its expression and a vaccinal vector comprising a sequence encoding a peptide or a polypeptide from

Helicobacter placed under the control of the elements necessary for its expression.

32. The method of Claim 31, in which the immunogenic agent derived from *Helicobacter* is the UreB or UreA subunit of the *Helicobacter* urease.

33. The method of Claim 31, in which the immunogenic agent derived from *Helicobacter* is a DNA molecule or a vaccinal vector comprising a sequence encoding the UreB or UreA subunit of the *Helicobacter* urease.

34. The method of Claim 31, 32, or 33, in which the immunogenic agent is derived from *Helicobacter pylori*.

35. The method of Claim 25, in which a mucosal adjuvant selected from the group consisting of *Escherichia coli* heat labile enterotoxin (LT), cholera toxin (CT), *Clostridium difficile* toxin, *Pertussis* toxin (PT), and combinations, subunits, toxoids, and mutants derived therefrom, is co-administered with the mucosally administered immunogenic agent.

36. The method of Claim 25, in which a parenteral adjuvant selected from the group consisting of alum, QS-21, DC-chol, and Bay is co-administered with the parenterally administered immunogenic agent.

Add B12